In re National Prescription Opiate Litigation: MDL 2804

DEFENDANTS' DAUBERT MOTION TO EXCLUDE THE OPINIONS OF SETH B. WHITELAW

Summary Sheet

Motion Name: Defendants' Daubert Motion to Exclude the Opinions of Seth B. Whitelaw

Concise Description:

Defendants move to exclude the opinions of Seth Whitelaw, proffered by plaintiffs as an expert on DEA suspicious order monitoring. Whitelaw lacks any experience with controlled substances, pharmaceutical distribution, the Controlled Substances Act, or the Drug Enforcement Administration ("DEA"). He never designed, operated or audited a suspicious order monitoring program for controlled substances. He never worked at DEA. He never worked for a pharmaceutical distributor or a manufacturer of controlled substances. Instead, Whitelaw is a food and drug attorney who advises clients on the routine regulations of the Food and Drug Administration. In short, Whitelaw lacks the qualifications, training, and experience to serve as an expert on DEA suspicious order monitoring programs. Indeed, Whitelaw admits that, prior to this litigation, he did not consider himself an expert in suspicious order monitoring.

In addition to being unqualified, his methodology is unreliable. Whitelaw created a model suspicious order monitoring program relying on a regulatory framework of his own invention that is not used either by those in the field or by DEA and was created solely for the purposes of this litigation. Whitelaw relies on what he describes as the "eight elements" of the Federal Sentencing Guidelines for organizations convicted of felonies and misdemeanors as the basis for his analysis. But the Federal Sentencing Guidelines are not about suspicious order monitoring or the diversion of prescription medications; instead, they provide courts with guidelines for the sentencing of organizations for felony and Class A misdemeanor offenses. Neither DEA nor industry participants—nor anyone else—uses the Federal Sentencing Guidelines to evaluate suspicious order monitoring programs.

Whitelaw's opinions are, in short, made up out of whole cloth as a litigation-based exercise with no grounding in the real world. This is confirmed by the fact that after Whitelaw was retained by plaintiffs in this case, he reversed his earlier published criticisms against the use of government guidance and standards as a basis for compliance programs.

Whitelaw should be excluded because he is not qualified to be an expert on DEA suspicious order monitoring programs, his opinions are unreliable, and he purports to usurp the role of the jury by opining on an ultimate issue.

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